U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Maternal and Child Health Bureau
Division of Services for Children with Special Health Needs

Severe Combined Immunodeficiency (SCID) Screening and Education

Funding Opportunity Number: HRSA-18-088
Funding Opportunity Type(s): New
Catalog of Federal Domestic Assistance (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

Application Due Date: March 13, 2018

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!
Deadline extensions are not granted for lack of registration.
Registration in all systems, including SAM.gov and Grants.gov,
may take up to 1 month to complete.

Issuance Date: January 11, 2018

Jill F. Shuger, ScM
Project Officer, Genetic Services Branch
Telephone: (301) 443-3247
Email: JShuger@hrsa.gov

Authority: Public Health Service Act, § 1109 (42 U.S.C. 300b-8), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240)

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), is accepting applications for fiscal year (FY) 2018 for the *Severe Combined Immunodeficiency (SCID) Screening and Education* program. The purpose of this program is to: 1) increase awareness and knowledge about SCID and newborn screening for SCID among parents, families, health care providers, public health professionals, and the public; 2) provide education, training, and support for newborn screening programs; 3) educate families with children diagnosed with SCID and link them to clinical and other services, especially those in rural and medically underserved areas; and 4) improve clinical care through education and training for providers caring for individuals with SCID.

The FY 2018 President's Budget does not request funding for this program. This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds a timely manner. You should note that this program may be cancelled prior to award recommendations.

Funding Opportunity Title:	Severe Combined Immunodeficiency (SCID) Screening and Education
Funding Opportunity Number:	HRSA-18-088
Due Date for Applications:	March 13, 2018
Anticipated Total Annual Available FY18 Funding:	$2,000,000
Estimated Number and Type of Award(s):	One grant
Estimated Award Amount:	Up to $2,000,000 per year
Cost Sharing/Match Required:	No
Project Period/Period of Performance:	August 1, 2018 through July 31, 2020 (2 years)
Eligible Applicants:	A state or a political subdivision of a state; a consortium of two (2) or more states or political subdivisions of states; a territory; a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or any other domestic entity with appropriate expertise in newborn screening, as determined by the Secretary. See Section III-1 of this notice of funding opportunity (NOFO), formerly known as the funding opportunity announcement (FOA), for complete eligibility information.

Application Guide

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide,* available online at http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this NOFO to do otherwise. A short video explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Technical Assistance

HRSA has scheduled the following technical assistance webinar. Please submit questions to the HRSA project officer listed on this NOFO prior to the call.

Webinar

Day and Date: Wednesday, January 24, 2018
Time: 12 - 1 p.m. ET
Call-In Number: 1-866-723-0810
Participant Code: 31341820#
Weblink: https://hrsa.connectsolutions.com/scid/

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I. Program Funding Opportunity Description

1. Purpose

This notice solicits applications for the Severe Combined Immunodeficiency (SCID) Screening and Education program. The purpose of this program is to: 1) increase awareness and knowledge about SCID and newborn screening for SCID among parents, families, health care providers, public health professionals, and the public; 2) provide education, training, and support for newborn screening programs; 3) educate families with children diagnosed with SCID and link them to clinical and other services, especially those in rural and medically underserved areas; and 4) improve clinical care through education and training for providers caring for individuals with SCID.

Program Goal:

The goal is to improve outcomes for infants with SCID detected through newborn screening by increasing awareness and knowledge about SCID, supporting state newborn screening programs, linking families, especially those living in rural and medically underserved areas, to services and developing long-term follow-up strategies for infants identified through newborn screening.

You should demonstrate knowledge about SCID, follow up and treatment of infants identified through newborn screening, and have experience working with state newborn screening programs, community based care providers, family support organizations, and SCID specialists.

Program Objectives:

The award recipient must be responsible for establishing baselines in the first year of the project. Baseline data may be calculated from a single point in time or based on an average over the first year of the project period. Data must be collected on the following program objectives at the end of years 1 and 2 for the purpose of monitoring and evaluating the overall effectiveness of the program.

- By 2020, increase by 10 percent annually the number of unique users/visitors accessing a web-based resource on SCID for families and health care providers.
- By 2020, increase by 10 percent annually the number of expectant parents, families, and providers that received education and awareness materials on SCID and SCID newborn screening that are linguistically and culturally appropriate.
- By 2020, increase by 10 percent annually the number of families with infants, especially those living in rural and medically underserved areas, identified through newborn screening that receive education on treatment and that are linked to SCID expert care centers for treatment, management, and follow-up services.
- By 2020, increase by 10 percent annually the number of trainings (education sessions and/or consultations) provided to healthcare providers who diagnose, treat, manage and care for individuals with SCID.

Program Requirements

To achieve the goals of this initiative, the SCID Screening and Education program award recipient will conduct the following activities:

- Establish a steering committee to provide support and guidance on implementing the goals and activities of the program. The steering committee should:
    a. Consist of families with children diagnosed with SCID, representatives of medically underserved populations, advocacy and support organizations, SCID treatment centers, and community-based primary and specialty care clinicians.
    b. Develop and implement strategies to identify critical issues and barriers to accessing quality services for individuals identified through newborn screening, especially those living in rural or underserved areas.
    c. Recommend strategies to increase awareness and understanding of SCID in underserved communities.
- Develop and maintain an online website that includes resources and materials on SCID that are linguistically and culturally sensitive and appropriate for diverse populations organized in a clear format. Information/materials should include:
    a. Information on the screening, diagnosis, treatment, and management of SCID;
    b. Grant-related information, materials, data, and educational opportunities;
    c. Links to state, federal, and national organizations related to SCID; and
    d. Links to services for families.
- Develop and disseminate linguistically and culturally appropriate education and awareness resources on SCID newborn screening directed to expectant parents, families, health care providers, public health professionals, and the public using various modalities.
- Support state SCID newborn screening implementation and maintenance through education or other resources to state newborn screening programs and staff.
- Develop a mechanism to link families with children with SCID, especially those in rural and underserved areas, to clinical centers with expertise to confirm the diagnosis and initiate evidence-based treatment and to other services needed by families.
- Engage families with children diagnosed with SCID in all aspects of the project including planning, implementation, and monitoring.
- Develop and disseminate information, education, training, consultation services and other resources to providers who care for individuals with SCID including primary care providers, specialists, emergency room physicians, school nurses, and others who care for individuals with SCID.
- Develop and implement mechanisms and protocols to obtain long-term follow-up information on the clinical outcomes of infants identified by newborn screening.
- Build partnerships with related stakeholder organizations, such as: 1) American College of Medical Genetics and Genomics; 2) Association of Public Health Laboratories (APHL); 3) American Academy of Pediatrics; 4) Primary Immune Deficiency Treatment Consortium; 5) Newborn Screening Clearinghouse; 6) Newborn Screening Translational Research Network; 7) Federally Qualified

Health Centers; 8) Parent to Parent USA; 9) Family Voices; 10) Family to Family Health Information Centers; 11) state health department newborn screening and follow-up programs; and 12) the Centers for Disease Control and Prevention, Newborn Screening and Molecular Branch.

- Support an annual meeting of partners, state newborn screening staff, specialists, primary care providers and families to share SCID activities and identify gaps in services.
- Work with the HRSA project officer to establish baseline data on the program objectives. It is required that all baseline data be reported to HRSA by the end of the first year of the grant.
- Develop an evaluation plan that includes the program objectives listed in the NOFO to monitor and evaluate program results.

2. Background

This program is authorized by Public Health Service Act, § 1109 (42 U.S.C. 300b-8), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240). Newborn screening is a successful public health program by which 4 million newborns each year are tested for conditions that are not apparent at birth but require early intervention and treatment to mitigate brain and organ damage, severe illness, and life-threatening complications associated with these conditions. States currently screen for at least 29 conditions on the Recommended Uniform Screening Panel (RUSP), a list of conditions recommended by the Secretary of Health and Human Services (HHS) for state newborn screening programs. In 2010, the Secretary of HHS accepted the Advisory Committee on Heritable Disorders in Newborns and Children's recommendation to add SCID to the RUSP. SCID is a primary immunodeficiency disorder, a life threating genetic disorder requiring early immune restorative treatment in the first year of life (http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/index.html).

HRSA has supported the wide-spread adoption of SCID newborn screening since 2014. In 2012, only six states screened for SCID. By 2017, 47 states and U.S. Territories screen for SCID.[1] Despite the success of SCID newborn screening, gaps remain in optimizing outcomes for infants with SCID as detected by newborn screening. Attendees of the 2017 APHL National SCID In-person Meeting held on August 8-9, 2017, identified the following as continuing needs: increased education for families; communication between the newborn screening laboratory, the pediatric immunology and infectious disease specialists, and primary care; and access to specialists, as SCID specialists are located largely in urban academic medical centers. This program will support activities to help the remaining states and territories screen newborns for SCID, increase education and awareness about SCID, and link families to services, especially those in rural and underserved communities.

[1] https://data.newsteps.org/newsteps-web/reports/screenedConditions/list.action Accessed 12/18/17

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a grant.

2. Summary of Funding

HRSA expects approximately $2,000,000 to be available annually to fund one recipient. You may apply for a ceiling amount of up to $2,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The actual amount available will not be determined until enactment of the final FY 2018 federal appropriation. The FY 2018 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. The project period is August 1, 2018 through July 31, 2020 (2 years). Funding beyond the first year is dependent on the availability of appropriated funds for S*evere Combined Immunodeficiency (SCID) Screening and Education* in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles and Audit Requirements at 45 CFR part 75.

III. Eligibility Information

1. Eligible Applicants

A state or a political subdivision of a state; a consortium of two or more states or political subdivisions of states; a territory; a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or any other domestic entity with appropriate expertise in newborn screening, as determined by the Secretary. Appropriate expertise is further explained in Section IV, ii. Program Narrative – Needs Assessment and Organizational Information and Section V's Review Criteria # (1) Need and (5) Resources/Capabilities.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this notice.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.4* will be considered non-responsive and will not be considered for funding under this notice.

Per the PHS Act § 1109(g) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other federal, state, and local public funds provided for activities of the type described in this section.

NOTE: Multiple applications from an organization are not allowable.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA ***requires*** you to apply electronically through Grants.gov. You must use the SF-424 application package associated with this NOFO following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

Effective December 31, 2017 - You **must** use the Grants.gov Workspace to complete the workspace forms and submit your application workspace package. After this date, you will no longer be able to use PDF Application Packages.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing the notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) or application package. This allows Grants.gov to email organizations that supply an email address in the event the NOFO is changed and/or republished on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the Find Grant Opportunities page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

Section 4 of HRSA's *SF-424 Application Guide* provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide* except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the *Application Guide* for the Application Completeness Checklist.

Application Page Limit
The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the application package do not count in the page limitation. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under this notice.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
3) Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in Attachment 7: Other Relevant Documents.

See Section 4.1 viii of HRSA's *SF-424 Application Guide* for additional information on all certifications.

Temporary Reassignment of State and Local Personnel during a Public Health Emergency

Section 201 of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), Public Law 113-5 amends section 319 of the Public Health Service (PHS) Act to provide the Secretary of the Department of Health and Human Services (HHS) with discretion to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency upon request by a state or tribal organization. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with section 319(e). This authority terminates September 30, 2018. Please reference detailed information available on the Assistant Secretary for Preparedness and Response (ASPR) website via http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

Program-Specific Instructions
In addition to application requirements and instructions in Section 4 of HRSA's *SF-424 Application Guide* (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), include the following:

i. Project Abstract
See Section 4.1.ix of HRSA's *SF-424 Application Guide*.

ii. Project Narrative
This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Successful applications will contain the information below. Please use the following section headers for the narrative:

- *INTRODUCTION -- Corresponds to Section V's Review Criterion(a) # (1) Need*
  Briefly describe the purpose of the proposed project. Be sure to include appropriate expertise with SCID, direct involvement in supporting implementation of SCID screening within state newborn screening programs, experience in working with families and medical professionals, and supporting a national network of medical centers to provide linkages to care for newborns diagnosed with SCID.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion(a) # (1) Need*
  This section will help reviewers understand the community, populations, individuals, or organizations or that you will serve with the proposed project.
  - Describe the target population(s) and their various needs. Include any socio-cultural determinants of health and health disparities impacting the populations or communities served, particularly in medically underserved areas.
  - Describe a national network of medical centers that provide care to newborns diagnosed with SCID.
  - Describe any relevant barriers and service gaps that the project hopes to overcome.
  - Describe the educational and service needs of families with SCID and the health care providers that serve them.
  - Use and cite demographic data whenever possible to support the information provided.

- *METHODOLOGY -- Corresponds to Section V's Review Criterion(a) # (2) Response*
  Propose methods that you will use to address the stated needs and meet each of the previously described program requirements and expectations in this NOFO. As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination with efforts to involve patients, families and communities, if applicable. Include a plan to disseminate reports, products, and/or project outputs so project information is provided to key target audiences.

You must also propose a plan for sustainability after the period of federal funding ends. HRSA expects recipients to sustain key elements of their projects, e.g., strategies or services and interventions, which have been effective in improving practices and those that have led to improved outcomes for the target population.

Please describe the methods you will use to implement the following activities:

- Establish a steering committee to provide support and guidance on implementing the goals and activities of the program. The steering committee should:
    - Consist of families with children diagnosed with SCID, representatives of medically underserved populations, advocacy and support organizations, SCID treatment centers, and community-based primary and specialty care clinicians.
    - Develop and implement strategies to identify critical issues and barriers to accessing quality services for individuals identified through newborn screening, especially those living in rural or underserved areas.
    - Recommend strategies to increase awareness and understanding of SCID in underserved communities.
- Develop and maintain an online website that includes resources and materials on SCID that are linguistically and culturally sensitive and appropriate for diverse populations organized in a clear format. Information/materials should include:
    - Information on the screening, diagnosis, treatment, and management of SCID;
    - Grant-related information, materials, data, and educational opportunities;
    - Links to state, federal, and national organizations related to SCID; and
    - Links to services for families.
- Develop and disseminate linguistically and culturally appropriate education and awareness resources on SCID newborn screening directed to expectant parents, families, health care providers, public health professionals, and the public using various modalities.
- Support state SCID newborn screening implementation and maintenance through education or other resources to state newborn screening programs and staff.
- Develop a mechanism to link families with children with SCID, especially those in rural and underserved areas, to clinical centers with expertise to confirm the diagnosis and initiate evidence-based treatment and to other services needed by families.
- Engage families with children diagnosed with SCID in all aspects of the project including planning, implementation, and monitoring.
- Develop and disseminate information, education, training, consultation services and other resources to providers who care for individuals with SCID including primary care providers, specialists, emergency room physicians, school nurses, and others who care for individuals with SCID.

- Develop and implement mechanisms and protocols to obtain long-term follow-up information on the clinical outcomes of infants identified by newborn screening.
- Build partnerships with related stakeholder organizations, including but not limited to: 1) American College of Medical Genetics and Genomics; 2) Association of Public Health Laboratories; 3) American Academy of Pediatrics; 4) Primary Immune Deficiency Treatment Consortium; 5) Newborn Screening Clearinghouse; 6) Newborn Screening Translational Research Network; 7) Federally Qualified Health Centers; 8) Parent to Parent USA; 9) Family Voices; 10) Family to Family Health Information Centers; 11) state health department newborn screening and follow-up programs; and 12) the Centers for Disease Control and Prevention, Newborn Screening and Molecular Branch.
- Support an annual meeting of stakeholders including primary care providers, specialists, families, and state newborn screening staff to share lessons learned and identify gaps in services.

- *WORK PLAN AND LOGIC MODEL-- Corresponds to Section V's Review Criterion(a) #(2) Response and (4) Impact*
  Describe the activities or steps that you will use to achieve each of the objectives proposed during the entire project period in the Methodology section. Use a time line that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application.

  You must submit a logic model for designing and managing the project. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this notice, the logic model should summarize the connections between the:
  - Goals of the project (e.g., objectives, reasons for proposing the intervention, if applicable);
  - Assumptions (e.g., beliefs about how the program will work and support resources on research, best practices, and experience);
  - Inputs (e.g., organizational profile, collaborative partners, key staff, budget, other resources);
  - Target population (e.g., the individuals to be served);
  - Activities (e.g., approach, listing key intervention, if applicable);
  - Outputs (i.e., the direct products or deliverables of program activities); and
  - Outcomes (i.e., the results of a program, typically describing a change in people or systems).

- *RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion(a) # (2) Response*
  Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges. The discussion should include, but not be limited to:
    - Challenges in getting the last states to implement newborn screening for SCID.
    - Reaching underserved populations to increase education and awareness of SCID newborn screening and in linking families with a newborn with SCID to services.
    - Engaging primary care providers in education or training related to SCID.
    - Challenges in establishing mechanism to obtain long-term outcomes information on infants with SCID detected through newborn screening.
    - Challenges in implementing program performance and data collection.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion(a) # (3) Evaluative Measures and (5) Resources/Capabilities*
  You must describe the plan for the program performance evaluation that will contribute to continuous quality improvement. The program performance evaluation should monitor ongoing processes and the progress towards the goals and objectives of the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key staff, budget, and other resources), key processes, and expected outcomes of the funded activities.

  You must describe the systems and processes that will support your organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. Describe the data collection strategy to collect, analyze and track data to measure process and impact/outcomes and explain how the data will be used to inform program development and service delivery. You must describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.

  Within the evaluation plan, HRSA expects you to provide a baseline within the first year of the project period and data on the following program objectives:

    - By 2020, increase by 10 percent annually the number of unique users/visitors accessing a web-based resource for families and health care providers on SCID.
    - By 2020, increase by 10 percent annually the number of expectant parents, families, and providers that received education and awareness materials on SCID and SCID newborn screening that are linguistically and culturally appropriate.

- By 2020, increase by 10 percent annually the number of families with infants, especially those living in rural and medically underserved areas, identified through newborn screening that receive education on treatment and that are linked to SCID expert care centers for treatment, management, and follow-up services.
- By 2020, increase by 10 percent annually the number of trainings (education sessions and/or consultations) provided to healthcare providers who diagnose, treat, manage and care for individuals with SCID.

The program should also report on:

- Number of individuals reached by education and awareness campaigns.
- Number of families linked to services.
- Number of families linked to services who are from rural or underserved populations.
- Number of providers trained or educated on SCID and appropriate follow-up procedures.
- Number of public health newborn screening laboratory and follow-up staff trained or educated about SCID screening and appropriate follow-up.

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion # (5) Resources/Capabilities*
  - Provide assurances that you will use the amounts received to adopt and implement the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary (required per the PHS Act, § 1109(c)). http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/index.html.

  - Succinctly describe your organization's current mission and structure, scope of current activities, including an organizational chart, and describe how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. Discuss your knowledge about follow up and treatment of infants identified with SCID through newborn screening, especially those in rural and underserved areas; clinical expertise to confirm the diagnosis; and evidence-based treatment and other services needed by families.

  - Describe your experience working with state newborn screening programs, community-based care providers, family support organizations, and SCID specialists. You should have at least 5 years of direct involvement in supporting implementation of SCID screening in state newborn screening programs.

  - Discuss your expertise in developing a national network of medical centers in order to facilitate linkages to care for newborns diagnosed with SCID.

  - Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all

costs to avoid audit findings. Describe how you assess and improve the unique needs of target populations of the communities you serve.

NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

Narrative Section	**Review Criteria**
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan and Logic Model	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative (below)	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

iii. Budget

See Section 4.1.iv of HRSA's *SF-424 Application Guide*. Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions included in the Application Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if the application is selected for funding, you will have a well-organized plan and by carefully following the approved plan can avoid audit issues during the implementation phase.

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the SCID Screening and Education program requires funding to support an annual meeting of partners, state newborn screening staff, specialists, primary care providers and families to share SCID activities and identify gaps in services.

The Consolidated Appropriations Act, 2017 (P.L. 115-31), Division H, § 202, states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." Please see Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in FY 2018, as required by law.

iv. Budget Narrative

See Section 4.1.v. of HRSA's *SF-424 Application Guide*.

v. Program-Specific Forms

Program-specific forms are not required for application.

vi. *Attachments*

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. You must clearly label **each attachment**.

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in Section IV. ii. Project Narrative. Include the required logic model in this attachment.

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's *SF-424 Application Guide)*

Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff.

Attachment 3: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch.

Attachment 4: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific)

Provide any documents that describe working relationships between your organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverable. Make sure you sign and date all letters of agreement.

Attachment 5: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of the project.

Attachment 6: Tables, Charts, etc.

To give further details about the proposal (e.g., Gantt or PERT charts, flow charts, etc.).

Attachments 7-15: Other Relevant Documents

Include here any other documents that are relevant to the application. Letters of support must be dated and specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.).

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d))**.**

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

The Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (http://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

For further details, see Section 3.1 of HRSA's *SF-424 Application Guide.*

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

4. Submission Dates and Times

Application Due Date

The due date for applications under this NOFO is *March 13, 2018 at 11:59 p.m. Eastern Time*.

See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

Severe Combined Immunodeficiency (SCID) Screening and Education is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's *SF-424 Application Guide* for additional information.

6. Funding Restrictions

You may request funding for a project period of up to 2 years, at no more than $2,000,000 per year (inclusive of direct **and** indirect costs). Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The FY 2018 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner.

The General Provisions in Division H of the Consolidated Appropriations Act, 2017 (P.L. 115-31) apply to this program. Please see Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in FY 2018, as required by law.

The recipient may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual support. Per the PHS Act, § 1109(e) LIMITATION, an eligible entity may not use amounts received under this section to—

(1) provide cash payments to or on behalf of affected individuals;
(2) provide inpatient services;
(3) purchase land or make capital improvements to property; or
(4) provide for proprietary research or training.

You are required to have the necessary policies, procedures and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all other applicable grants requirements, the effectiveness of these policies, procedures and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award under the program will be addition. Post-award requirements for program income can be found at 45 CFR § 75.307.

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. Critical indicators have been developed for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria are outlined below with specific detail and scoring points.

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The Severe Combined Immune Deficiency (SCID) Screening and Education program has a number of review criteria:

Criterion 1: NEED (10 points) – Corresponds to Section IV's Introduction and Needs Assessment
The extent to which the application:

- Describes the purpose of the proposed project and includes appropriate expertise with SCID, direct involvement in supporting implementation of SCID screening within state newborn screening programs, experience in working with families and medical professionals, and supporting a national network of medical centers that provide care to newborns diagnosed with SCID. (7 points)

- Describes and documents the target population(s) and unmet educational, resource, and support needs, including the needs of various underserved populations, as well as specific barriers that exist that prevent this population from gaining knowledge about or access to services for SCID. Describes and documents the needs of health care providers who care for individuals and families with SCID. Uses and cites demographic data whenever possible to support the information provided. Includes any relevant barriers in the service area that the project hopes to overcome as well as socio-cultural determinants of health and health disparities impacting the populations or communities served that are unmet. (3 points)

Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's Methodology, Work Plan and Logic Model, and Resolution of Challenges

The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives. The extent to which the applicant describes an effective approach to:

- Establishing a steering committee made up of families with children diagnosed with SCID, representatives of medically underserved populations, advocacy and support organizations, SCID treatment centers, and community-based primary and specialty care clinicians to provide support and guidance on implementing the goals and activities of the program. Developing and implementing strategies to identify critical issues and barriers to accessing quality services for individuals identified through newborn screening, especially those living in rural or underserved areas. (3 points)

- Increasing awareness and understanding of SCID in underserved communities. (3 points)

- Developing and maintaining an online website that includes resources and materials on SCID that are linguistically and culturally sensitive and appropriate for diverse populations organized in a clear format. Information/materials should include (3 points):
    - Information on the screening, diagnosis, treatment, and management of SCID;
    - Grant-related information, materials, data, and educational opportunities;
    - Links to state, federal, and national organizations related to SCID; and
    - Links to services for families.

- Developing and disseminating linguistically and culturally appropriate education and awareness resources on SCID newborn screening directed to expectant parents, families, health care providers, public health professionals, and the public using various modalities. (3 points)

- Supporting state SCID newborn screening implementation and maintenance through education or other resources to state newborn screening programs and staff. (3 points)

- Developing a mechanism to link families with children with SCID, especially those in rural and underserved areas, to clinical centers with expertise to confirm the diagnosis and initiate evidence-based treatment and to other services needed by families. Engaging families with children diagnosed with SCID in all aspects of the project including planning, implementation, and monitoring. (6 points)

- Developing and disseminate information, education, training, consultation services and other resources to providers who care for individuals with SCID including primary care providers, specialists, emergency room physicians, school nurses, and others who care for individuals with SCID. Developing and implementing mechanisms and protocols to obtain long-term follow-up information on the clinical outcomes of infants identified by newborn screening. (3 points)
- Building partnerships with related stakeholder organizations, including but not limited to: 1) American College of Medical Genetics and Genomics (ACMG); 2) Association of Public Health Laboratories (APHL); 3) American Academy of Pediatrics (AAP); 4) Primary Immune Deficiency Treatment Consortium (PIDTC); 5) Newborn Screening Clearinghouse; 6) Newborn Screening Translational Research Network (NBSTRN); 7) Federally Qualified Health Centers (FQHC); 8) Parent to Parent USA P2P USA); 9) Family Voices (FV); 10) Family to Family Health Information Centers (F2FIC); 11) state health department newborn screening and follow-up programs; and the Centers for Disease Control and Prevention (CDC), Newborn Screening and Molecular Branch. (3 points)

- Resolving challenges, related to: (3 points)
    - Identifying states that have not implemented newborn screening for SCID and challenges associated with implementation.
    - Reaching underserved populations to increase education and awareness of SCID newborn screening and link families with a newborn with SCID to services.
    - Engaging primary care providers in education or training related to SCID.
    - Establishing a mechanism to obtain long-term outcomes information on infants with SCID detected through newborn screening.
    - Implementing program performance and data collection.

Criterion 3: EVALUATIVE MEASURES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity
The strength and effectiveness of the method proposed to monitor and evaluate the project results.

The extent to which the applicant:

- Describes the plan for evaluation that monitors ongoing processes and the progress towards the goals and objectives of the project. (5 points)
- Describes the evaluative methods that will be able to assess:

    - To what extent the program objectives have been met, and
    - To what extent these can be attributed to the project (5 points)

- Describes the data collection strategy to collect, analyze and track data to measure progress on performance objectives. (5 points)

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Work Plan and Logic Model

The extent to which the applicant demonstrates:

- The feasibility and effectiveness of plans for dissemination of project results. (3 points)
- The extent to which project results may be national in scope. (4 points)
- The degree to which the project activities are replicable, and the sustainability of the program beyond the period of federal funding. (3 points)

Criterion 5: RESOURCES/CAPABILITIES (30 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information

The extent to which the applicant:

- Describes the organization's current mission and structure, scope of current activities, including an organizational chart, and describes how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. Describes how the project personnel are qualified by training and/or experience to implement and carry out the program. (5 points)
- Describes expertise in developing a national network of medical centers in order to facilitate linkages to care for newborns diagnosed with SCID. (10 points)
- Provides information on the program's resources and capabilities to support provision of culturally and linguistically competent and health literate services and materials. Describes how the organization has the capacity to meet the unique needs of target populations of the communities served. (5 points)
- Demonstrates experience working with newborn screening stakeholders including families, medical professionals, state newborn screening programs, community based organizations, and the general public and reaching and working with diverse populations. Describes at least 5 years of direct involvement in supporting implementation of SCID screening in state newborn screening programs. (10 points)

Criterion 6: SUPPORT REQUESTED (5 points) – Corresponds to Section IV's Budget and Budget Narrative

The reasonableness of the proposed budget for each year of the project period in relation to the objectives, the complexity of the research activities, and the anticipated results.

- The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.
- Support an annual meeting of stakeholders including primary care providers, specialists, families, and state newborn screening staff to share lessons learned and identify gaps in services.

2. Review and Selection Process

The independent review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. In addition to the ranking based on merit criteria, HRSA approving officials may also apply other factors in award selection, (e.g., geographical distribution), if specified below in this NOFO. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

See Section 5.3 of HRSA's *SF-424 Application Guide* for more details.

3. Assessment of Risk and Other Pre-Award Activities

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (45 CFR § 75.205).

Applications receiving a favorable objective review are reviewed for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA will make an award, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

A determination that an applicant is not qualified will be reported by HRSA to FAPIIS (45 CFR § 75.212).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of August 1, 2018.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of August 1, 2018. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2.2 of HRSA's *SF-424 Application Guide*.

Human Subjects Protection:
Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR part 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

3. Reporting

The new Discretionary Grant Information System (DGIS) reporting system will continue to be available through the Electronic Handbooks (EHBs). HRSA enhanced the DGIS and these improvements are available for recipient reporting as of October 1, 2017. Once the new DGIS has been developed, tested, and deployed, HRSA will communicate with recipients and provide instructions on how to access the system for reporting. HRSA will also provide technical assistance via webinars, written guidance, and one-on-one sessions with an expert, if needed.

The updated and final reporting package incorporating all OMB-accepted changes can be reviewed at (OMB Number: 0915-0298 Expiration Date: 06/30/2019):

https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection.

Award recipients must comply with Section 6 of HRSA's *SF-424 Application Guide* **and** the following reporting and review activities:

1) **Progress Report(s)**. The recipient must submit a progress report to HRSA on an **annual** basis, which should address progress against

program outcomes, including any expected outcomes in the first year of the program. Further information will be provided in the award notice.

2) **Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.

3) **Performance Reports.** HRSA has modified its reporting requirements for Special Projects of Regional and National Significance projects, Community Integrated Service Systems projects, and other grant/cooperative agreement programs to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). GPRA requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act.

a) Performance Measures and Program Data

To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program can be found at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/SC1_1.HTML.

Administrative Forms			
Form 1, Project Budget Details Form 2, Project Funding Profile Form 4, Project Budget and Expenditures Form 6, Maternal & Child Health Discretionary Grant Products, Publications, and Submissions Data Collection Form TA/Collaboration Form			
Updated DGIS Performance Measures, Numbering by Domain *(All Performance Measures are revised from the previous OMB package)*			
Performance Measure	**New/Revised Measure**	**Prior PM Number (if applicable)**	**Topic**
Core			
Core 1	New	N/A	Grant Impact
Core 2	New	N/A	Quality Improvement
Core 3	New	N/A	Health Equity – MCH Outcomes

Capacity Building			
CB 2	New	N/A	Technical Assistance
CB 3	New	N/A	Impact Measurement
CB 4	Revised	5	Sustainability
CB 6	New	N/A	Products
Children and Youth with Special Health Care Needs			
CSHCN 1	Revised	7	Family Engagement
CSHCN 2	Revised	40, 41	Access to and Use of Medical Home

b) Performance Reporting Timeline

Successful applicants receiving HRSA funds will be required, within 120 days of the project start date, to register in HRSA's EHBs and electronically complete the program-specific data forms that are required for this award. This requirement entails the provision of budget breakdowns in the financial forms based on the award amount, the project abstract and other grant summary data as well as providing objectives for the performance measures.

Performance reporting is conducted for each year of the project period. Recipients will be required, within 120 days of the budget period start date, to enter HRSA's EHBs and complete the program-specific forms. This requirement includes providing expenditure data, finalizing the abstract and grant summary data as well as finalizing indicators/scores for the performance measures.

c) Project Period End Performance Reporting

Successful applicants receiving HRSA funding will be required, within 90 days from the end of the project period, to electronically complete the program-specific data forms that appear for this program. The requirement includes providing expenditure data for the final year of the project period, the project abstract and grant summary data as well as final indicators/scores for the performance measures.

4) **Integrity and Performance Reporting.** The Notice of Award will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

VII. Agency Contacts

You may request additional information regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Mary Worrell
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-5181
Email: mworrell@hrsa.gov

You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Jill Shuger, ScM
Project Officer
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18W09D
Rockville, MD 20857
Telephone: (301) 443-3247
Email: jshuger@hrsa.gov

You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
Email: support@grants.gov
Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center
Telephone: (877) 464-4772
TTY: (877) 897-9910
Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Logic Models

Additional information on developing logic models can be found at the following website: http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. Information on how to distinguish between a logic model and work plan can be found at the following website: http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf.

Technical Assistance

HRSA has scheduled the following technical assistance webinar. Please submit questions to the HRSA project officer listed on this NOFO prior to the call.

Webinar

Day and Date: Wednesday, January 24, 2018
Time: 12 - 1 p.m. ET
Call-In Number: 1-866-723-0810
Participant Code: 31341820#
Weblink: https://hrsa.connectsolutions.com/scid/

IX. Tips for Writing a Strong Application

See Section 4.7 of HRSA's *SF-424 Application Guide*.